

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness referred to exercise therapy unit in outpatient setting

Protocol summary

Study aim

The effect of exercise therapy and lifestyle modification training on the components of metabolic syndrome in patients with severe mental illness

Design

Pretest-posttest

Settings and conduct

The patient's overall performance is determined by the Global Assessment of Functioning (GAF). The patient is checked for metabolic syndrome and the patient's height, weight, blood pressure and waist circumference are measured and BMI is determined and recorded and the patient's level of physical activity is determined based on the interview and 6 min walk test is performed. Some lab tests including fasting blood sugar and lipid profile are requested. 1) 20 sessions of exercise therapy 2) 4 group training sessions of lifestyle modification The lifestyle modification sessions are held by a trained nurse every week in a group manner. The duration of each session is about 45-30 minutes. Patients attend exercise therapy sessions under the supervision of a trainer twice a week for 10 weeks. At the end of 10 weeks, the patient's overall function is determined again and the fasting blood sugar assessment and lipid profile are repeated. The patient's BMI, blood pressure, and waist circumference are measured and recorded again after 5 weeks and at the end of week 10.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe mental illness, in the age range of 18-50 years, in the remission phase and under the medication treatment Exclusion criteria: Patients with a history of substance abuse in the past month, unstable physical or neurological disorders, patients with diabetes mellitus or heart disease, uncontrolled seizures or musculoskeletal disease

Intervention groups

The intervention includes 20 sessions of exercise therapy

and 4 sessions of a nutrition education program.

Main outcome variables

weight BMI Waist circumstances Blood pressure FBS and lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210703051765N1**

Registration date: **2021-09-16, 1400/06/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-16, 1400/06/25**

Update count: **0**

Registration date

2021-09-16, 1400/06/25

Registrant information

Name

Zahra Mirsepassi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8838 5809

Email address

mirsepassizahra@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-04, 1400/04/13

Expected recruitment end date

2023-07-04, 1402/04/13

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness referred to exercise therapy unit in outpatient setting

Public title
The effect of exercise therapy and lifestyle modification on metabolic syndrome components in patients with severe mental illness

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with severe mental illness In the remission phase Under the treatments
Exclusion criteria:
Substance use in the last month Presence of any uncontrolled medical or neurological disease Diabetes mellitus Heart disease Uncontrolled seizure Musculoskeletal disease

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address

Tehran University of Medical Sciences, Poorsina Ave,
Ghods Ave, Enghelab Ave

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-06-22, 1400/04/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.320

Health conditions studied

1

Description of health condition studied

schizophrenia

ICD-10 code

F20

ICD-10 code description

Schizophrenia

2

Description of health condition studied

schizoaffective disorder

ICD-10 code

F25

ICD-10 code description

Schizoaffective disorders

3

Description of health condition studied

bipolar disorder

ICD-10 code

F31

ICD-10 code description

Bipolar disorder

4

Description of health condition studied

depressive disorders without psychotic feature

ICD-10 code

F32.2

ICD-10 code description

Major depressive disorder without psychotic features

5

Description of health condition studied

depressive disorders with psychotic feature

ICD-10 code

F32.3

ICD-10 code description

Major depressive disorder with psychotic features

Primary outcomes

1

Description

Waist circumference

Timepoint

Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy

Method of measurement

Centimeter tape measure

2

Description

Weight

Timepoint

Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy

Method of measurement

Scale

3

Description

Blood Glucose

Timepoint

Before starting the intervention and after 20 sessions of exercise therapy

Method of measurement

Lab tests

4

Description

Lipid profile

Timepoint

Before starting the intervention and after 20 sessions of exercise therapy

Method of measurement

Lab tests

5

Description

Systolic blood pressure

Timepoint

Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy

Method of measurement

Sphygmomanometer

6

Description

Diastolic Blood pressure

Timepoint

Before starting the intervention/after 10 sessions of exercise therapy/after 20 sessions of exercise therapy

Method of measurement

Sphygmomanometer

Secondary outcomes

1

Description

Global assessment of functioning

Timepoint

Before the intervention/at the end of the intervention

Method of measurement

GAF scale

Intervention groups

1

Description

The intervention includes exercise therapy and a nutrition education program. The nutrition educational program includes 4 group educational sessions. The intervention to increase physical activity includes 20 sessions of exercise therapy. Nutrition education program: In the first 4 sessions, patients will participate in a group educational session and then receive exercise therapy intervention. In the following sessions, the individual's nutritional habits will be explored and then exercise therapy will be provided. The training sessions will be held by a trained nurse, occupational therapist or psychologist who has participated in a workshop. These sessions are held every week in a group manner (5-8 people). The duration of each session will be about 30-45 minutes. The first session includes being familiar with the team members and reviewing the basics principles of healthy eating. In the second and third sessions, different food categories, the fiber content of foods, different food calories and the importance of physical activity will be explained. In the fourth session, in addition to review the previous contents, the patients' misconceptions about nutrition, will be discussed. The exercise therapy as an intervention to increase physical activity: The exercise program including 5 to 10 minutes of warm-up (low-intensity exercise with flexibility movements), 15 to 30 minutes of aerobic exercise includes stationary and elliptical cycling, 15 minutes of strength training with the device for upper and lower limbs and 5 minutes of cooling. Exercise intervention will be the same for all patients, and aerobic exercise and moderate-intensity strength exercise will be defined according to the Borg table (between 11 and 14). Exercise therapy sessions will be performed twice a week for 10 weeks (20 sessions of exercise therapy) under the supervision of a trained trainer. The patient's vital signs will be recorded by the nurse, before and after the intervention. The exercise program will be performed under the supervision of a coach for 30-45 minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Exercise therapy unit in Roozbeh Hospital

Full name of responsible person

Zahra Mirsepassi

Street address

Roozbeh hospital, South Kargar Ave, Tehran, Iran

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Tehran

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Web page address<https://roozbehhospital.tums.ac.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr shahin Akhondzadeh

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s.akhond@neda.net

Web page address<http://medicine.tums.ac.ir/research>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepassi

Position

Assistant professor of psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Roozbeh Hospital, South Kargar Ave, Tehran, Iran

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Web page address<https://roozbehhospital.tums.ac.ir>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Zahra Mirsepassi

Position

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Web page address<https://roozbehhospital.tums.ac.ir>**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

According to ethical concerns the data will not be

published.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Publication as a manuscript

When the data will become available and for how long

Three years later

To whom data/document is available

The researchers

Under which criteria data/document could be used

Planning for health promotion

From where data/document is obtainable

The journal

What processes are involved for a request to access data/document

Requesting via email

Comments